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THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

STEVE ELLIS, et al.,

Plaintiffs,

v.

STEVEN P. BRADBURY, et al.,

Defendants,

and

BAYER CROPSCIENCE LP, SYNGENTA CROP PROTECTION, LLC, VALENT U.S.A. CORPORATION, AND CROPLIFE AMERICA,

Defendant-Intervenors.

Case No. 3:13-cv-01266-MMC

BAYER CROPSCIENCE LP, SYNGENTA CROP PROTECTION, LLC, VALENT U.S.A. CORPORATION, AND CROPLIFE AMERICA'S NOTICE OF MOTION TO DISMISS AND FOR JUDGMENT ON THE PLEADINGS; AND MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF

(Fed. R. Civ. P. 12)
Date: December 6, 2013
Time: 9:00 a.m.
Place: Courtroom 7, 19th Floor

Honorable Maxine M. Chesney

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NOTICE OF MOTION AND MOTION

Notice is hereby given that on December 6, 2013, or as soon as this matter may be heard before the Honorable Maxine M. Chesney in Courtroom 7 of the 19th Floor of 450 Golden Gate Avenue, San Francisco, California, Defendant-Intervenors Bayer CropScience LP, Syngenta Crop Protection, LLC, Valent U.S.A. Corporation, and CropLife America ("Intervenors"), will and hereby do jointly move this Court to dismiss Claim 1 in part and Claims 2-14 in their entirety.

Pursuant to Civil L.R. 7-2, Intervenors respectfully move to dismiss portions of Claim 1 and Claims 2-14 for lack of subject matter jurisdiction pursuant to FRCP 12(b)(1), and in the alternative, for judgment on the pleadings on the ground that these Claims fail to state a claim upon which relief may be granted under FRCP 12(c) and 12(b)(6). In support of this Motion, Intervenors submit the accompanying Memorandum of Points and Authorities, Declaration, and Exhibits 1-3.

POINTS AND AUTHORITIES IN SUPPORT OF MOTION

I. INTRODUCTION

Plaintiffs present 14 claims asking this Court to invalidate over 100 existing pesticide product registrations. With one possible exception, this Court lacks subject matter jurisdiction as Plaintiffs' claims are either currently pending before EPA for final action, or were never presented to EPA in the first instance. Even without these fatal jurisdictional flaws, the Amended Complaint fails to state a claim due to Plaintiffs' consistent failures to allege a cognizable claim for relief, to identify the final agency action under challenge, to exhaust the issues in the administrative process, and to bring suit within the applicable six-year statute of limitations period. For these and the numerous other reasons set forth below, Claims 2-14 and part of Claim 1 should be dismissed for lack of jurisdiction, or in the alternative for failure to state a claim. Intervenors also join in EPA's Motion to Dismiss filed on July 31, 2013 [Dkt. #59] ("EPA Motion"), which is incorporated by reference.

II. BACKGROUND

A. Statutory and Regulatory Background

For the sake of brevity, Intervenors do not provide a separate overview of FIFRA and the ESA to supplement EPA's overview. *See* EPA Mot. at 1-5. Where particular features of these statutes bear emphasis or were not addressed by EPA, they are noted in the Argument.

B. EPA's Comprehensive and Ongoing Review of the Challenged Pesticide Products, Which Are Critical to Agriculture

Clothianidin and thiamethoxam have revolutionized agriculture and provide tremendous economic and environmental benefits to the nation's farmers and consumers. Growers rely on these products to protect millions of acres of crops in the United States every year from insect pests. *See* Am. Compl. ¶ 2. For example, in 2012, either clothianidin or thiamethoxam was applied to protect nearly 90% of the corn seed planted, the nation's largest crop by acreage.

Before registration, these pesticide active ingredients were subject to a comprehensive multi-year EPA assessment based on the extensive health and environmental data on each compound. EPA issued the first thiamethoxam registration in December 2000, and the first clothianidin registration in May 2003. *See id.* ¶ 79, App. B at 4, App. A at 7. Today, each is registered for a wide range of agricultural and other uses. EPA is currently in the midst of the statutory Registration Review process for both clothianidin and thiamethoxam, and issued Final Work Plans for each of these pesticides in mid-2012. *See id.* ¶ 96.[1]

Registration Review is a comprehensive assessment process conducted by EPA on each registered pesticide, in which EPA gathers additional scientific information (including by requiring the submission of additional data from registrants) and determines whether the pesticide continues to meet the standard for registration under FIFRA. At the same time, Registration Review provides the mechanism for EPA and the Services[2] to ensure ESA compliance for the over 1,100 pesticide active ingredients[3] contained in tens of thousands of registered products, through a systematic, comprehensive, and transparent process. Starting in the mid-2000s, EPA accelerated its efforts to "[a]ssess potential risks to listed species during [the] course of overall ecological risk assessment for registration review."[4] According to EPA, incorporating species assessments and consultation into

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[1] http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2011-0581 (thiamethoxam); http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2011-0865 (clothianidin).

[2] *I.e.*, the U.S. Fish and Wildlife Service ("FWS") and the National Marine Fisheries Service ("NMFS").

[3] *See* www.epa.gov/oppsrrd1/registration_review/highlights.htm.

[4] "Protecting Endangered Species," Presentation by EPA's Office of Pesticide Programs, at 6 (May 22, 2008), *available at* www.epa.gov/pesticides/ppdc/2008/may2008/session9.pdf.

Registration Review is beneficial because it: results in "[d]ecisions [that] address potential risk to *all* listed species; provides pesticide users with certainty; takes advantage of existing public participation processes; and provides [the] broadest protection" of listed species.[5]

C. Procedural History

1. The Petition to Cancel Clothianidin, and EPA's Partial Decision

As indicated by EPA, four of the Plaintiffs submitted an "Emergency Citizen Petition" dated March 20, 2012 (the "Petition"), demanding that EPA suspend the registration of clothianidin within 90 days, initiate the cancellation process under FIFRA §6, and issue an order requiring the recall of all existing product and prohibiting its use. *See* EPA Mot., Ex. A (copy of Petition); *id.* at 5-6; Am. Compl. ¶ 82. The Petition presents at least four claims also alleged in the Amended Complaint:

- clothianidin's registration poses an "imminent hazard" to honey bees, requiring immediate suspension of the registrations and initiation of cancellation proceedings to remove the product from the market;
- a condition of registration requiring a pollinator field study was not met in a "reasonably sufficient" time, requiring suspension and cancellation;
- the product label directions for use inadequately protect bees, and EPA should declare "misbranded" all existing product and issue an order prohibiting its use and requiring a nationwide recall; and
- EPA failed to consult with the Services under ESA §7 when it first registered clothianidin in 2003, and should suspend the registration of clothianidin products until a consultation is completed.

Pet. at 5-6, 31-39; *compare* Am. Compl., Counts 1, 5, 11, 13.

EPA issued a 12-page Partial Decision on July 17, 2012, addressing and rejecting the claim of an "imminent hazard" to bees, and denying the request for immediate suspension of clothianidin registrations on that ground. The accompanying 30-page Technical Support Document, prepared by EPA scientists, details EPA's painstaking assessment of the data and the scientific and regulatory basis for the Partial Decision. *See* Ex. 1 (Partial Decision) & Ex. 2 (Technical Support Document).

EPA then published and solicited public comment on the Petition, its Partial Decision, and the Technical Support Document. *See* EPA, Clothianidin: Emergency Petition to Suspend: Notice of

[5] *Id.* (emphasis added).

Availability, 77 Fed. Reg. 44233 (July 27, 2012). EPA sought comment on: (1) the merits of the remaining claims in the Petition; and (2) whether EPA should reconsider its Partial Decision. EPA will consider the comments along with submissions received after the Partial Decision record closed, and issue a decision on both the rest of the Petition and whether to reconsider the Partial Decision. *Id.*

2. The Lack of a Petition to Cancel Thiamethoxam or Any EPA Decision

Instead of filing a similar petition to cancel thiamethoxam, three Plaintiffs submitted a letter to EPA in October 2012, entitled "comment and notice — risks of insecticide thiamethoxam" ("Comment Letter"), asserting that the same arguments in the clothianidin Petition also apply to thiamethoxam. EPA Mot., Ex. H. At least three of the claims in the Comment Letter are also alleged in the Amended Complaint, Claims 6, 11, and 14. Plaintiffs incorrectly assert that in EPA's response letter, dated February 27, 2013, EPA "refused that [thiamethoxam] suspension request also." Am. Compl. ¶ 88. To the contrary, EPA's letter merely "acknowledge[d] receipt" of the Comment Letter, and confirmed that it would be placed in the Registration Review docket and considered by EPA as part of that process. *See* Ex. 3.

3. The Amended Complaint

Plaintiffs allege 14 Claims against EPA, and ask that this Court declare the registrations illegal and vacate them, issue an order requiring EPA "to immediately suspend" the registrations, "enjoin any further use of the insecticides" pending EPA completion of ESA consultations, and "[e]njoin [any] proposed new clothianidin and thiamethoxam product uses." Am. Compl. ¶¶ 168-74. Although not always clear, as grounds for this relief, Plaintiffs allege that:

Claim 1. EPA acted arbitrarily and capriciously in issuing its Partial Decision by not "fully" considering the likelihood of an imminent hazard, and by not considering Plaintiffs' untimely supplemental filings as part of that Decision, and EPA has "unreasonabl[y] delay[ed]" deciding whether to reconsider the Partial Decision. *Id.* ¶¶ 102-05.

Claim 2. EPA violated the ESA by failing to consult with the Services under ESA §7 in reaching the Partial Decision, and failing to satisfy its "continuing obligation" to consider endangered species impacts. *Id.* ¶¶ 106-09.

Claims 3 and 4. EPA did not publish a "notice of receipt of application" or "notice of issuance" for some registration approvals, and did not make registration data public. *Id.* ¶¶ 110-19.

Claims 5 and 6. EPA "has been arbitrary and capricious and violated FIFRA's conditional registration provisions" by allowing the continued existence of conditional registrations for clothianidin and thiamethoxam products, imposing "impermissibly vague" conditions of registration, allowing more than a "reasonable time" for satisfaction of conditions of registration, and "unreasonably delay[ing]" the initiation of cancellation proceedings "for up to nine years" for clothianidin and "up to eleven years" for thiamethoxam. *Id.* ¶¶ 120-27.

Claims 7 and 8. EPA's reclassification of some registrations as unconditional, "while maintaining the conditional registrations for numerous other clothianidin [or thiamethoxam] products" with "outstanding data gaps and conditions," is arbitrary and capricious and "is in violation of" FIFRA's conditional registration requirements. *Id.* ¶¶ 128-39.

Claims 9 and 10. EPA's "ongoing failure to suspend" the registrations violates FIFRA and the Administrative Procedure Act ("APA") due to the products' unreasonable adverse effects on the environment. *Id.* ¶¶ 140-49.

Claims 11 and 12. The EPA-approved product labels are "inconsistent across various registered products" and "do not adequately protect bees," and thus "[i]t is arbitrary and capricious for EPA to continue to rely" on the labels. *Id.* ¶¶ 150-57.

Claims 13 and 14. EPA failed to consult with FWS and take related steps, before registering 35 clothianidin products over 10 years and 68 thiamethoxam products over 13 years, and continuously thereafter based on an "ongoing action" theory, in violation of ESA §7. Plaintiffs also allege that EPA allowed the "take" of listed species, in violation of ESA §9. *Id.* ¶¶ 158-68, 173.

III. STANDARD OF REVIEW

A. Dismissal for Lack of Subject Matter Jurisdiction and Failure to State a Claim

The applicable standards of review are summarized by EPA. *See* EPA Mot. at 9-11. This Motion is styled as a motion for judgment on the pleadings because Intervenors filed Answers as required to intervene. [Dkt. 37, 55]. Nonetheless, the same FRCP 12(b)(6) standard governing failure to state a claim applies. *Chavez v. United States*, 683 F.3d 1102, 1108 (9th Cir. 2012).

B. Jurisdiction Over Plaintiffs' Claims Is Determined by FIFRA §16

Because Plaintiffs challenge registrations issued under FIFRA, this Court's jurisdiction is governed by the specific judicial review provisions of FIFRA §16. Review is not available directly under the APA and general federal question jurisdiction. *Wilson v. Comm'r*, 705 F.3d 980, 990 (9th Cir. 2013) ("Where Congress has enacted a special statutory review process for administrative action, that process applies to the exclusion of the APA."). Jurisdiction over Plaintiffs' ESA citizen suit claims is also determined by FIFRA §16, not the ESA.[6]

C. The Deferential APA Standard of Review

Although judicial review directly under the APA is unavailable, the APA nevertheless furnishes the standard of review in the absence of a specific standard in FIFRA §16. *See Am. Paper Inst. v. Am. Elec. Power Serv. Corp.*, 461 U.S. 402, 413 (1983). Under the APA standard, the reviewing court is to uphold the challenged agency action unless it is arbitrary and capricious, or contrary to law. *Siskiyou Reg'l Educ. Project v. U.S. Forest Serv.*, 565 F.3d 545, 554 (9th Cir. 2009).

IV. ARGUMENT

A. This Court Lacks Subject Matter Jurisdiction Over Part of Claim 1 and All of Claims 2-14

Plaintiffs present a jumble of 14 vaguely-pled Claims, each of which (with one partial exception) falls within one of three procedurally-deficient categories:

- Claims presented to EPA in the Petition, that were subjected to notice-and-comment, and are now pending before EPA for decision (Claims 5, 11, 13, and part of 1);
- Claims presented to EPA in the Comment Letter, filed in the public docket for EPA resolution in the thiamethoxam Registration Review process (Claims 6, 12, 14); and
- Claims never presented to EPA (Claims 2, 3, 4, 7, 8, 9, 10).

[6] *See, e.g.*, *Am. Bird Conservancy v. FCC*, 545 F.3d 1190, 1194 (9th Cir. 2008); *Ctr. for Biological Diversity v. EPA*, Case No. 11-cv-00293-JCS, 2013 U.S. Dist. LEXIS 57436, at *54-56 (N.D. Cal. Apr. 22, 2013) ("*CBD v. EPA*") ("Although Plaintiffs only challenge the EPA's failure to consult under ESA § 7, Plaintiffs' core objections are to the pesticide registrations themselves . . . .") (internal quotations omitted).

More broadly, except the part of Claim 1 challenging EPA's Partial Decision as arbitrary and capricious (Am. Compl. ¶¶ 103-04), none of the claims were decided by EPA in denying a petition to cancel, and none satisfies the basic prerequisites for judicial review in any court.

1. This Court Lacks Jurisdiction Over the Petition Claims (5, 11, and 13), Because They Were the Subject of a "Public Hearing" by EPA

FIFRA §16 vests exclusive jurisdiction in the court of appeals to review EPA decisions issued "following a public hearing." 7 U.S.C. § 136n(b). Public notice and an opportunity for written comment constitute a "public hearing" under FIFRA §16. *United Farm Workers v. EPA*, 592 F.3d 1080, 1082-84 (9th Cir. 2010). Thus, as EPA correctly states, this Court lacks jurisdiction over Plaintiffs' allegations in Claim 1 that EPA has "unreasonably delayed" considering Plaintiffs' untimely submissions and deciding whether to "reconsider" its Partial Decision. *See* EPA Mot. at 12-16. Because those matters were subjected to notice-and-comment, EPA's future final decisions on these matters, and any claim of "unreasonable delay" regarding such decisions, will be reviewable exclusively in the court of appeals under FIFRA §16(b) and established case law. *See id*.

Similarly, the merits of Claims 5, 11, and 13 were also subjected to notice-and-comment as part of the Petition. EPA may issue a final decision on the Petition at any time, and exclusive jurisdiction over that future decision will rest in the court of appeals. *Amvac Chem. Corp. v. EPA*, 653 F.2d 1260, 1263 (9th Cir. 1980) (FIFRA §16 "limit[s] review of [EPA] decisions issued after [a] hearing to the Circuit Courts"). It would be inconsistent with FIFRA §16 to conclude that the same claims could simultaneously be presented for review in this Court. Such an interpretation should be avoided, with any uncertainty resolved in favor of placing jurisdiction at the court of appeals level. *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 745 (1985).

The Petition plainly contains the substance of Claims 5, 11, and 13. *Compare*, Am. Compl. ¶¶ 121-22 (conditions of registration requiring a "pollinator field study" were not met within a "reasonably sufficient" period), *with* Pet. at 5, 31-33 (condition of registration unmet due to "missing pollinator field study" and because a "reasonably sufficient" period had passed); *compare* Am. Compl. ¶ 151 (alleging labels are "not adequate to protect health and the environment"); *with* Pet. at 5-6, 36-39 (same); *compare* Am. Compl. ¶¶ 159-60 (alleging EPA failure to consult under ESA §7,

and a "take" of listed species); *with* Pet. at 6, 39 (same). Because EPA held a "public hearing" on these Claims, exclusive jurisdiction resides in the court of appeals under FIFRA §16(b).

2. Claims 3-14 Challenge the Validity of FIFRA Registrations, and Must Be Presented in a Petition and Decided by EPA Before Judicial Review

Plaintiffs' Claims 3-14 challenge the validity of existing FIFRA registrations. As courts have consistently held, Congress intended FIFRA §6 to be the sole mechanism for cancelling a FIFRA registration, with judicial review available only from an EPA denial of a petition to cancel. This Court should reject Plaintiffs' attempt to bypass the key environmental and agricultural safeguards in FIFRA §6 by effectively seeking cancellation directly in federal court.[7]

a. Congress Intended FIFRA §6 to Provide the Exclusive Mechanism for Cancelling a Registration

The registration of a pesticide "shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the Act," unless and until cancellation proceedings are initiated under FIFRA §6. 7 U.S.C. § 136a(f)(2). Thus, "Congress intended that FIFRA [§6] provides the *exclusive* means of cancelling a registration." *Defenders of Wildlife v. EPA*, 882 F.2d 1294, 1299 (8th Cir. 1989) (citations omitted) (emphasis added).

Section 6 establishes the comprehensive administrative process required to suspend or cancel an existing registration. EPA may initiate the process whenever it appears, from a petition or otherwise, that a registered pesticide no longer meets the registration standard. 7 U.S.C. § 136d(b). Before cancellation can occur, however, EPA "shall" solicit input from the Department of Agriculture ("USDA") on the agricultural impacts of cancellation, including "on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy." *Id.* § 136d(b)(2). EPA "shall" also obtain the input of an independent Scientific Advisory Panel

[7] Only Plaintiffs' "imminent hazard" allegation in Claim 1 was presented in a petition and decided by EPA in the Partial Decision, and thus is the only claim for which judicial review was available in any court. Arguably, however, that jurisdiction resided exclusively in the court of appeals. Although the Partial Decision was issued without public notice-and-comment, interested parties had the opportunity for written submissions. *See, e.g.*, *Nw. Food Processors v. Reilly*, 886 F.2d 1075, 1077 (9th Cir. 1989) (finding a "public hearing" under §16(b) where "EPA conducts proceedings in which interested parties are afforded an opportunity to present their positions by written briefs and a sufficient record is produced to allow judicial review.").

("SAP") "as to the impact on health and the environment" of the proposed cancellation. *Id.* §§ 136d(b), 136w(d).

In creating FIFRA §6, Congress expressly recognized that removing an existing crop protection tool from the market by cancelling the registration can significantly impact agriculture and the environment — core interests the statute is intended to protect. Such impacts may not be discernible without input from other agencies and bodies, including USDA and SAP, with special expertise and knowledge. Congress entrusted cancellation decisions to EPA's expertise in the first instance, through a unique process that ensures the development of critical facts and consideration of the impacts *before* any registration is cancelled. Section 6 provides that only "[f]inal orders of [EPA] under this section shall be subject to judicial review." *Id.* § 136d(h).

b. The Language of FIFRA §16(a) Limits District Court Jurisdiction to the Review of a Final EPA Petition Decision

Section 16(a) provides district court jurisdiction to review "the refusal of the Administrator to cancel or suspend a registration . . . not following a hearing and other final agency actions . . . not committed to the discretion of the Administrator by law." *Id.* § 136n(a). The explicit provision for district court review of an EPA denial of a petition to cancel or suspend confirms that a claim seeking the same relief directly in court is precluded. *See, e.g., United States v. Erika, Inc.*, 456 U.S. 201, 206-08 (1982) (Medicare statute, which expressly provided for judicial review of awards under Part A, was interpreted to preclude review of awards under Part B). Given the specific provision granting jurisdiction over an EPA "refusal" to cancel or suspend, the remaining language of §16(a) can only be read to confer review over claims "other" than those seeking cancellation or suspension. Any other reading would render the more specific language superfluous. *See United States v. Barajas-Alvarado*, 655 F.3d 1077, 1087 (9th Cir. 2011) ("[W]e are bound by the 'fundamental canon of statutory construction that a statute should not be construed so as to render any of its provisions mere surplusage.'") (citation omitted).

In addition, FIFRA §16(a) must be interpreted in conjunction with the cancellation process of §6 and the statute as a whole. Here, the "congressional intent to preclude judicial review" of claims seeking cancellation that are not first presented to EPA in a petition is "fairly discernible" from the

statutory scheme. *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 351 (1984); *id.* at 345 ("Whether and to what extent a particular statute precludes judicial review is determined not only from its express language, but also from the structure of the statutory scheme, its objectives, its legislative history, and the nature of the administrative action involved.").

c. Courts Have Consistently Concluded That a Final EPA Decision on a Petition to Cancel Is a Prerequisite to Judicial Review

Thus, courts that have considered the issue have concluded that a plaintiff who effectively seeks cancellation or suspension of a FIFRA registration must first submit a petition to cancel, and may obtain judicial review only of EPA's final decision on the petition. The Ninth Circuit's reasoning in the landmark decision of *Merrell v. Thomas* is highly instructive. 807 F.2d 776 (9th Cir. 1986). The plaintiff in that case, Paul Merrell, "sued to enjoin the EPA from continuing to register seven herbicides," claiming that "the registrations were invalid" and had been issued by EPA contrary to law. *Id.* at 776. The Court scoured the statutory scheme and legislative history, and found that Congress struck a "careful balance" between providing appropriate opportunities for public input and judicial review of EPA decisions, and streamlining the registration process and minimizing litigation to "accommodate[] agriculture's need for pesticides" *Id.* at 779, 780.

Critically, the Ninth Circuit concluded that "FIFRA provides for substantial public participation *only after* a pesticide is registered" through the petition to cancel process. *Id*. at 782 (emphasis added) As the Court noted, "that does not mean that Merrell is without a remedy," because "FIFRA contains procedures for cancelling or suspending pesticide registrations," and "district courts may review refusals to cancel or suspend registration." *Id.* at 781-82. The Court rejected Merrell's objection that, because EPA "ultimately has discretion whether to initiate the process for suspending or cancelling a registration," a petition to cancel should not be required. *Id.* at 782.

For Plaintiffs, as for Merrell, the path to challenge an existing EPA pesticide registration in federal court was made clear by the Ninth Circuit more than 25 years ago:

> The fact that FIFRA provides for substantial public participation only after a pesticide is registered does not make its review procedures illusory or worthless. In particular, FIFRA could provide Merrell with relief in this case.

> Merrell does not complain of pending applications for pesticide registration. Rather, he attacks use registrations for seven pesticides, most of which were approved years ago. . . . Cancellation or suspension of pesticide registrations therefore would be a suitable remedy.
>
> Although FIFRA vests considerable discretion in the Administrator [of EPA], interested persons can influence his decisions through petitions . . . .

Id. The court noted that "[e]nvironmental organizations have acted under these notice and review provisions to challenge EPA refusals to cancel or suspend pesticide registrations." *Id.*

Similarly, the Eighth Circuit rejected a plaintiff's effort to challenge three existing registrations, holding that the plaintiff's "remedy lies in petitioning the EPA to cancel the three challenged registrations," and "[i]f the EPA refuses to cancel, [the plaintiff] may seek judicial review in the district court." *Defenders of Wildlife*, 882 F.2d at 1298; *id.* at 1302 ("Defenders could petition the EPA to cancel registrations or request other action. If the EPA refused, Defenders could obtain judicial review in the district court as provided by FIFRA."). Thus, plaintiffs seeking to cancel a registration must "proceed under the FIFRA framework," which "provides the exclusive means of cancelling a registration." *Id.* at 1299.[8]

Other courts have similarly concluded that any claim that effectively seeks the cancellation or suspension of a registration must first be presented to EPA in a petition to cancel. *See Merrell v. Thomas*, 608 F. Supp. 644, 647 (D. Or. 1985) ("The relief which plaintiff seeks in this action is, in effect, the cancellation or suspension of the registrations of the pesticides named in the complaint. FIFRA provides the exclusive mechanism to obtain this relief."), *affirmed*, 807 F.2d 776; *Hardin v. BASF Corp*., 290 F. Supp. 2d 964, 972 (E.D. Ark. 2003) ("If Plaintiffs believe that the EPA erred in registering Facet, they may petition the EPA to cancel the registration. If Plaintiffs are unsuccessful, they may obtain judicial review of the EPA's final decision denying their request."), *vac'd on other grounds*, 397 F.3d 1082 (8th Cir. 2005); *see also Reckitt Benckiser v. Jackson*, 762 F. Supp. 2d 34, 43-44, 46 (D.D.C. 2011) (holding that EPA may use only FIFRA §6, and not the threat of a misbranding enforcement action, to remove a product from the market that it no longer considers eligible for registration, and finding that FIFRA's legislative history "confirms that Congress

[8] Separately, *Defenders of Wildlife* found ESA citizen suit jurisdiction not governed by FIFRA §16. *Id.* at 1301. This aspect of the case is not the law in the Ninth Circuit. *See* fn 6, *supra*.

intended EPA to use the Section 6 cancellation process to remove registered products from the market for failing to meet the FIFRA's registration standard").

Here, Plaintiffs' Claims 3-14 indisputably challenge the validity of existing FIFRA registrations and seek to have this Court vacate them. Because Plaintiffs did not first petition EPA to cancel the registrations and obtain a final EPA decision, the Claims must be dismissed.

3. Claims 5-6 and 11-14 Are Not Ripe

The ripeness doctrine "prevent[s] the courts, through avoidance of premature adjudication from entangling themselves in abstract disagreement over administrative policies," and "protect[s] agencies from judicial interference until an administrative decision has been formalized." *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 732-33 (1998). Claims still under consideration by the agency, even as part of an administrative process that was not mandatory, are generally not ripe for judicial review. *See, e.g., Acura of Bellevue v. Reich*, 90 F.3d 1403, 1407-09 (9th Cir. 1996) (non-mandatory appeal of Department of Labor decision rendered the agency's action non-final and unripe for review); *Ukiah Valley Med. Ctr. v. FTC,* 911 F.2d 261, 264 n.1 (9th Cir. 1990) (agency action was not final or ripe for review due to pending determination by the agency that could moot the case).

Here, "the possibility that further consideration will actually occur . . . is not theoretical, but real" and hearing the claims now would "interfere with the system that Congress specified" under FIFRA that charges EPA with addressing registration, cancellation, and suspension issues in the first instance. *Ohio Forestry Ass'n*, 523 U.S. at 735-36. As discussed above, Claims 5, 11, and 13 are currently pending before EPA for decision as part of the Petition, and Claims 6, 12, and 14 are pending before EPA for decision as part of the Registration Review process for thiamethoxam.[9] These claims do not raise "purely legal" questions for which no "further administrative proceedings are contemplated." *Abbot Labs. v. Gardner*, 387 U.S. 136, 149 (1967). Rather, resolving these

[9] Similarly, the comprehensive Registration Review process underway at EPA for both clothianidin and thiamethoxam encompasses all of the FIFRA and ESA issues raised in Claims 3-14, arguably providing an independent basis to dismiss *all* of these Claims as unripe. *See, e.g., Acura of Bellevue*, at 1408-09.

claims "would require time-consuming judicial consideration of the details of an elaborate, technically based" record and regulatory regime. *Ohio Forestry Ass'n*, 523 U.S. at 736. In addition, hearing the claims now would deprive the Court of the benefit of a complete administrative record. EPA solicited and will consider public comments in deciding the Petition, and is gathering extensive data and other relevant material that it will consider in deciding the issues raised in the Comment Letter as part of the Registration Review process.

Moreover, having an agency and the Court "simultaneously review an agency action wastes scarce governmental resources" and "poses the possibility that an agency authority and a court would issue conflicting rulings." *Acura of Bellevue*, at 1408-09 (finding judicial review unavailable during administrative hearing). "Allowing judicial review in the middle of the agency review process unjustifiably interferes with the agency's right to consider and possibly change its position during its administrative proceedings." *Id.* at 1409. For these reasons, the Petition and Comment Letter claims, which are currently pending before EPA for decision, are not ripe for review and should be dismissed.

4. Plaintiffs Lack Article III Standing to Bring Their ESA Claims (2, 13-14)

Plaintiffs have not demonstrated Article III standing to pursue any of their ESA claims. *See* Am. Compl. ¶¶ 106-09, 158-67. Accordingly, the Court should dismiss Claims 2 and 13-14 in their entirety. "[T]o satisfy Article III's standing requirements, a plaintiff must show: (1) [it] has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth v. Laidlaw Envtl. Servs., Inc.*, 528 U.S. 167, 180–81 (2000). Plaintiffs "must demonstrate standing for each claim [they] seek[] to press and for each form of relief sought." *Oregon v. Legal Servs. Corp.*, 552 F.3d 965, 969 (9th Cir. 2009) (internal quotations and citations omitted). The facts showing standing must be "clearly apparent on the face of the complaint." *Baker v. United States*, 722 F.2d 517, 518 (9th Cir. 1983).

The Amended Complaint fails to meet these standards. Plaintiffs' ESA claims chiefly allege that EPA failed to consult with the FWS under ESA §7(a)(2) concerning whether EPA actions on clothianidin and thiamethoxam were likely to jeopardize ESA-listed species. To satisfy the standing requirements for these claims, Plaintiffs must plead with specificity the species and their geographical areas, pesticides, and agency actions at issue. *CBD v. EPA*, 2013 U.S. Dist. LEXIS 57436, *37-38. In *CBD v. EPA*, the Court dismissed ESA consultation and jeopardy claims by environmental groups on precisely these grounds:

> Plaintiffs do not . . . allege any facts in connection to Plaintiffs' or the members' injury with regard to their interests in any *particular species or geographical area* affected by any particular pesticide.
>
> Plaintiffs must bring a separate ESA claim in connection with the *EPA's affirmative act* with regard to *each individual pesticide* in order to invoke Section 7's consultation requirement. It follows that Plaintiffs must also allege facts supporting standing for each individual claim.

Id. at *38 (emphases added) (citing *Oregon*, 552 F.3d at 969; *Allen v. Wright*, 468 U.S. 737, 752 (1984)).

Plaintiffs fail to plead adequately on any of these elements. As to species and their localities, Plaintiffs allege harm to broad swaths of species, but identify by name only 18 listed species. *See* Am. Compl. ¶ 73 (alleging harm to insect species that "include, but are not limited to," the 18 Plaintiffs identify); *id*. ¶ 74 (alleging effects on "non-insect ESA-listed species," but not naming any); *id.* ¶ 77 (alleging injury to a "broad suite of birds, as well as to aquatic invertebrates" without naming any or alleging that they are ESA-listed species). Because "standing is not dispensed in gross," *CBD v. EPA*, 2013 U.S. Dist. LEXIS 57436, at *39 (quoting *Lewis v. Casey*, 518 U.S. 343, 358 n.6 (1996)), Plaintiffs have not pled standing as to any of the unnamed species.

Likewise, as to the 18 identified species, Plaintiffs fail to allege specific facts which, if substantiated, would establish their interest in each of these geographically limited species, and fail to allege which, if any, of the challenged pesticides is used in those areas. These species exist only in certain, often very limited, localities scattered across the country. For example, FWS's endangered species database (www.fws.gov/endangered/) shows that the Salt Creek tiger beetle is

known or believed to occur only in two counties in Nebraska, and the Zayante band-winged grasshopper in two counties in Florida. Plaintiffs have not pled these or any other localities where each named species may exist, let alone facts to support standing for those localities. Am. Compl. ¶ 73.[10]

In addition, as to the pesticides and EPA's alleged actions, Plaintiffs catalogue over 100 EPA activities (in Appendices A and B) but fail to allege how each harms any of the 18 species, or how each species is harmed by any of the EPA activities. Rather, they allege only that the 18 species are "potentially directly affected," without tying those alleged effects to any specific EPA action. Am. Compl. ¶ 73. Similarly, Plaintiffs claim "direct and indirect mortality risks" for a "broad suite of birds," but no nexus between the alleged effects and a particular EPA action. *Id.* ¶ 77. These vague and general allegations lack the critical causal nexus needed to establish Article III standing. *See Wash. Toxics Coal. v. EPA*, No. C01-132C, 2002 U.S. Dist. LEXIS 27654, at *22-37 (W.D. Wash. July 2, 2002) (standing doctrine narrowed suit from over 900 pesticides to the 54 pesticides where plaintiffs proffered limited evidence of injury to ESA-listed salmon); *see also CBD v. EPA*, 2013 U.S. Dist. LEXIS 57436, at *38 ("Plaintiffs must bring a separate ESA claim in connection with the EPA's affirmative act with regard to each individual pesticide . . . ."). Plaintiffs' ESA claims should be dismissed.

5. Plaintiffs Failed to Provide Sufficient Notice of Their ESA Claims

Intervenors join EPA's argument that this Court lacks jurisdiction over the ESA claims that Plaintiffs failed to include in the "Sixty-Day Notice of Intent to Sue Pursuant to the Endangered Species Act" ("Notice Letter"). *See* EPA Mot. at 19-21, 31-32; *Sw. Ctr. for Biological Diversity v. U.S. Bureau of Reclamation*, 143 F.3d 515, 520 (9th Cir. 1998) (ESA notice requirement is jurisdictional). The following ESA claims must be dismissed as not mentioned in the Notice Letter: (1) Claim 2, alleging EPA failure to analyze effects and consult with FWS in issuing the Partial

[10] Plaintiffs must affirmatively allege that they "use the area affected by the challenged activity and not an area roughly 'in the vicinity' of it." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 565 (1992) (citation omitted); *Citizens for Better Forestry v. U.S. Dep't of Agric.*, 341 F.3d 961, 971 (9th Cir. 2003) ("[E]nvironmental plaintiffs must allege that they will suffer harm by virtue of their geographic proximity to and use of areas that will be affected . . . .").

Decision; (2) the allegations in Claims 13-14 that EPA approvals "take" species in violation of ESA §9 (Am. Compl. ¶¶ 162, 167, 173); (3) all claims regarding the 17 registrations not mentioned in the Notice Letter (*see* EPA Mot., Ex. K); and (4) all claims by Plaintiffs Jim Doan, Bill Rhoads, and Center for Environmental Health, who were not parties to the Notice Letter. *See* EPA Mot., Ex. E.

B. Failure to State a Claim Upon Which Relief May Be Granted

Even if the Court had subject matter jurisdiction, in the alternative Claims 2-14 should be dismissed for failure to state a claim.

1. Claims 2-4 and 7-10 Raise Issues Never Presented to EPA, and Should Be Dismissed as Waived for Lack of Issue Exhaustion

A basic premise of judicial review is that arguments and issues not presented to the agency in an available administrative process are generally waived, and cannot be raised for the first time in court. This doctrine of "issue exhaustion" is closely related to primary jurisdiction, finality, and ripeness. In general, "[a] reviewing court usurps the agency's function when it sets aside the administrative determination upon a ground not theretofore presented." *Duncan-Harrelson Co. v. Dep't of Labor*, 644 F.2d 827, 832 (9th Cir. 1981) (citation omitted); *see also, e.g.*, *Lands Council v. McNair*, 629 F.3d 1070, 1076 (9th Cir. 2010) ("A party forfeits arguments that are not raised during the administrative process."); *Advocates for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin.*, 429 F.3d 1136, 1150 (D.C. Cir. 2005) ("The administrative waiver doctrine, commonly referred to as issue exhaustion, provides that it is inappropriate for courts reviewing agency decisions to consider arguments not raised before the administrative agency involved."); *Nuclear Energy Inst., Inc. v. EPA*, 373 F.3d 1251, 1297 (D.C. Cir. 2004) (per curiam) ("It is a hard and fast rule of administrative law, rooted in simple fairness, that issues not raised before an agency are waived and will not be considered by a court on review.").

As the D.C. Circuit has explained, "it is unsurprising that parties rarely are allowed to seek 'review' of a substantive claim that has never even been presented to the agency for its consideration," given that "the role of the court is to determine whether the agency's decision is arbitrary and capricious for want of reasoned decisionmaking." *Advocates for Highway & Auto Safety*, 429 F.3d at 1149-50; *id.* ("[A] court is not to substitute its judgment for that of the agency.").

Requiring that arguments be presented during the administrative process allows an agency "to exercise its expertise," "to correct any mistakes," and to avoid "unnecessary or premature judicial intervention into the administrative process." *Buckingham v. Dep't of Agric.*, 603 F.3d 1073, 1080 (9th Cir. 2010) . Here, Plaintiffs waived Claims 2-4 and 7-10 by failing to present them to EPA, despite multiple opportunities to do so.

2. Claims 3-4 (Notice and Data Availability)

In Claims 3 and 4, Plaintiffs allege that EPA did not publish in the Federal Register a "notice of receipt of application" for "the vast majority" of registrations and use approvals, did not publish a "notice of issuance" promptly after every registration, and did not make public the underlying data within 30 days after registration. Am. Compl. ¶¶ 111-18.

a. Claims Relating to Notices Allegedly Required Before March 21, 2007, Are Barred by the Statute of Limitations

As FIFRA §16(a) does not include its own statute of limitations, the general statute applies, under which a civil action against the United States "shall be barred" unless filed within "six years after the right of action first accrues." 28 U.S.C. § 2401(a); *Hardin v. Jackson*, 625 F.3d 739, 742 (D.C. Cir. 2010). Here, the notice claims alleged by Plaintiffs first accrued on the date each registration issued, if not earlier.[11] *See Wind River Mining Corp. v. United States*, 946 F.2d 710, 715 (9th Cir. 1991) ("If a person wishes to challenge a mere procedural violation in the adoption of a regulation or other agency action, the challenge must be brought within six years of the decision."). Thus, at a minimum, Plaintiffs' notice challenges involving registrations issued before March 21, 2007 (six years before this action commenced), are barred. Thirty of the challenged registrations were issued before that date. *See* Am. Compl. ¶¶ 112, 117.

b. Plaintiffs Fail to Allege Prejudice From Any "Missing" Notice

Plaintiffs have failed to allege how any lack of a "notice of receipt of an application" or "notice of issuance" within the six-year limitations period could have prejudiced Plaintiffs, or

[11] A notice of receipt of application is due "promptly" after EPA receives the application to register a new use. The registration would issue months or years later. Thus, even more of Plaintiffs' claims are time-barred depending on the specific application date for each registration.

affected any EPA registration decision. In this regard, it is useful to note that a "notice of receipt of an application" occurs shortly after an application is received, and thus before EPA's substantive review of the data. Such a notice merely identifies the applicant, the name of the new chemical, and its proposed uses.

Whenever a court reviews agency action, "due account shall be taken of the rule of prejudicial error." 5 U.S.C. § 706; *Brock v. Pierce Cnty.*, 476 U.S. 253, 260 (1986) ("[Not] every failure of an agency to observe a procedural requirement voids subsequent agency action . . . ."). This is "the same kind of 'harmless-error' rule that courts ordinarily apply in civil cases." *Shinseki v. Sanders*, 556 U.S. 396, 406 (2009).

The Supreme Court's *Shinseki* decision is on point. In *Shinseki*, the plaintiff challenged a denial of benefits based on the agency's failure to issue a statutorily-required notice after receiving a benefits application. *Shinseki*, 556 U.S. at 399. The Federal Circuit held that it is "presumed" that such a lack of notice is prejudicial, and placed the burden on the agency to establish that the error did not affect its decision. *Id.* at 403-04. The Supreme Court reversed, holding that whether an error is harmless cannot be determined through mandatory presumptions, but must be assessed based "on the facts and circumstances of the particular case." *Id.* at 408. In addition, "the burden of showing that an error is harmful normally falls upon the party attacking the agency's determination." *Id.* at 409; *see also Molina v. Astrue*, 674 F.3d 1104, 1111 (9th Cir. 2012); *Tongass Conservation Soc'y v. U.S. Forest Serv.*, 455 F. App'x 774, 777 (9th Cir. 2011) ("[T]o set aside an agency decision as being based upon an error, the plaintiff must show that the error was not harmless.").

The Court held that the lack of notice was harmless error where the plaintiff had not explained "what specific additional evidence proper notice would have led him to obtain or seek" or "how the notice error . . . could have made any difference" to the agency's decision. *Shinseki*, 556 U.S. at 413. On those facts, the harmlessness of the notice error was not a close question. *Id.* ("The Veterans Court did not consider the harmlessness issue a borderline question. Nor do we.").

So too here. Plaintiffs identify no information that could have been submitted to EPA, but was not, due to an alleged lack of a notice. To the contrary, Plaintiffs concede that EPA issued a

number of formal notices in the Federal Register soliciting comment on EPA's ongoing consideration and approval of new uses of both pesticides, listing three notices for clothianidin and six for thiamethoxam. *See* Am. Compl., Apps. A, B.

Moreover, Plaintiffs' lists are woefully incomplete. In fact, EPA published 34 Federal Register notices on its clothianidin registration activities over the years, starting in 2001, with 11 soliciting comment on applications for registrations,[12] and 23 soliciting comment on, or announcing the establishment of, the clothianidin tolerances required to register each crop use.[13] *See* 21 U.S.C. § 346a(a)-(c) (requiring an EPA tolerance decision to allow registration of a pesticide for each food use). For thiamethoxam, EPA published 45 Federal Register notices from 1999 forward, with eight soliciting comment on EPA's receipt of applications for registrations,[14] and 37 soliciting comment on, or announcing the establishment of, the thiamethoxam tolerances required to register each crop use.[15] This Court can take judicial notice of administrative records, including Federal Register

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[12] 74 Fed. Reg. 50198 (Sept. 30, 2009); 74 Fed. Reg. 54999 (Oct. 26, 2009); 74 Fed. Reg. 58957 (Nov. 16, 2009); 75 Fed. Reg. 20841 (Apr. 21, 2010); 75 Fed. Reg. 32767 (June 9, 2010); 75 Fed. Reg. 34114 (June 16, 2010); 75 Fed. Reg. 51045 (Aug. 18, 2010); 76 Fed. Reg. 26291 (May 6, 2011); 76 Fed. Reg. 39396 (July 6, 2011); 77 Fed. Reg. 13599 (Mar. 7, 2012); 77 Fed. Reg. 59186 (Sept. 6, 2012).

[13] 66 Fed. Reg. 57079 (Nov. 14, 2001); 68 Fed. Reg. 32390 (May 30, 2003); 68 Fed. Reg. 75504 (Dec. 31, 2003); 69 Fed. Reg. 33635 (June 16, 2004); 69 Fed. Reg. 71036 (Dec. 8, 2004); 70 Fed. Reg. 7886 (Feb. 16, 2005); 70 Fed. Reg. 74003 (Dec. 14, 2005); 71 Fed. Reg. 74795 (Dec. 13, 2006); 72 Fed. Reg. 21261 (Apr. 30, 2007); 73 Fed. Reg. 6851 (Feb. 6, 2008); 73 Fed. Reg. 51817 (Sept. 5, 2008); 73 Fed. Reg. 73640 (Dec. 3, 2008); 74 Fed. Reg. 16866 (Apr. 13, 2009); 74 Fed. Reg. 20947 (May 6, 2009); 74 Fed. Reg. 65021 (Dec. 9, 2009); 75 Fed. Reg. 28009 (May 19, 2010); 75 Fed. Reg. 35801 (June 23, 2010); 76 Fed. Reg. 7712 (Feb. 11, 2011); 76 Fed. Reg. 25240 (May 4, 2011); 76 Fed. Reg. 76674 (Dec. 8, 2011); 77 Fed. Reg. 52246 (Aug. 29, 2012); 77 Fed. Reg. 59578 (Sept. 28, 2012); 78 Fed. Reg. 19130 (Mar. 29, 2013).

[14] 64 Fed. Reg. 14233 (Mar. 24, 1999); 64 Fed. Reg. 56500 (Oct. 20, 1999); 74 Fed. Reg. 54999 (Oct. 26, 2009); 75 Fed. Reg. 13282 (Mar. 19, 2010); 75 Fed. Reg. 24695 (May 5, 2010); 75 Fed. Reg. 51045 (Aug. 18, 2010); 75 Fed. Reg. 53691 (Sept. 1, 2010); 76 Fed. Reg. 39396 (July 6, 2011).

[15] 64 Fed. Reg. 24153 (May 5, 1999); 65 Fed. Reg. 54019 (Sept. 6, 2000); 65 Fed. Reg. 79755 (Dec. 20, 2000); 65 Fed. Reg. 80343 (Dec. 21, 2000); 66 Fed. Reg. 28386 (May 23, 2001); 66 Fed. Reg. 64828 (Dec. 14, 2001); 67 Fed. Reg. 43310 (June 27, 2002); 67 Fed. Reg. 66561 (Nov. 1, 2002); 68 Fed. Reg. 16040 (Apr. 2, 2003); 68 Fed. Reg. 51471 (Aug. 27, 2003); 68 Fed. Reg. 54386 (Sept. 17, 2003); 69 Fed. Reg. 31110 (June 2, 2004); 69 Fed. Reg. 55506 (Sept. 15, 2004); 70 Fed. Reg. 708 (Jan. 5, 2005); 70 Fed. Reg. 7177 (Feb. 11, 2005); 71 Fed. Reg. 39316 (July 12, 2006); 72 Fed. Reg. 34401 (June 22, 2007); 73 Fed. Reg. 13225 (Mar. 12, 2008); 73 Fed. Reg. 20632 (Apr. 16,

notices, in deciding this Motion to Dismiss. *See Barron v. Reich*, 13 F.3d 1370, 1377 (9th Cir. 1994).

These 79 total Federal Register entries provided ample notice to Plaintiffs and the public that EPA was considering and issuing new crop use approvals for clothianidin and thiamethoxam products. Fifty-three of these notices explicitly requested public comment, and all 79 of them afforded opportunities for public input or other action. Plaintiffs simply ignored these notices. (Many of the notices confirm that no comments at all were received). Under these circumstances, it is difficult to imagine how a small number of additional Federal Register notices could possibly have changed the information considered by EPA, or any other aspect of its decision-making.

Moreover, given the statute of limitations, to state a cognizable claim Plaintiffs must show prejudice from a "missing" notice allegedly required after March 21, 2007. By that time, EPA had already published 26 formal notices regarding clothianidin and thiamethoxam registrations,[16] including notices specific to the use of these products on the very crops that Plaintiffs allege are frequented by bees for forage and pollination, including corn and pome fruit for clothianidin,[17] and corn, pome fruit, fruiting vegetables, turf, sod, cucurbits, ornamentals, sunflower, stone fruits, and beans for thiamethoxam.[18] *See* Am. Compl. ¶¶ 16-18, 20. Plaintiffs ignored these notices as well.

Plaintiffs fail to allege how a few additional Federal Register entries during the past six years could possibly have caused prejudice. They fail to identify a single piece of relevant information that could have been submitted in response to an additional notice (but not in response to the 79

2008); 73 Fed. Reg. 21043 (Apr. 18, 2008); 74 Fed. Reg. 15869 (Apr. 8, 2009); 74 Fed. Reg. 16866 (Apr. 13, 2009); 74 Fed. Reg. 41898 (Aug. 19, 2009); 74 Fed. Reg. 50137 (Sept. 30, 2009); 75 Fed. Reg. 864 (Jan. 6, 2010); 75 Fed. Reg. 14154 (Mar. 24, 2010); 75 Fed. Reg. 32463 (June 8, 2010); 75 Fed. Reg. 35653 (June 23, 2010); 75 Fed. Reg. 48667 (Aug. 11, 2010); 76 Fed. Reg. 10584 (Feb. 25, 2011); 76 Fed. Reg. 36479 (June 22, 2011); 76 Fed. Reg. 50904 (Aug. 17, 2011); 76 Fed. Reg. 53372 (Aug. 26, 2011); 77 Fed. Reg. 12731 (Mar. 2, 2012); 77 Fed. Reg. 50661 (Aug. 22, 2012); 77 Fed. Reg. 75082 (Dec. 19, 2012); 78 Fed. Reg. 18511 (Mar. 27, 2013).

[16] Eight clothianidin notices and 18 thiamethoxam notices regarding registration and tolerance actions were published before March 21, 2007. *See* fns. 12-15, *supra*.

[17] *See* 68 Fed. Reg. 32390 (May 30, 2003); 70 Fed. Reg. 7886 (Feb. 16, 2005).

[18] *See* 64 Fed. Reg. 14233 (Mar. 24, 1999), 64 Fed. Reg. 54500 (Oct. 20, 1999), 67 Fed. Reg. 66561 (Nov. 1, 2002), and 68 Fed. Reg. 54386 (Sept. 17, 2003).

notices EPA did provide), and fail to explain how that could have impacted the outcome of a single EPA registration decision. Claims 3 and 4 fail to state a claim upon which relief can be granted.

c. Plaintiffs' Bare Allegation of an EPA Failure to Make Data Available to the Public Fails to State a Claim

As EPA correctly explains, it is required only to make the data underlying its registration decisions available "upon request." 40 C.F.R. § 152.119(c); *see* EPA Mot. at 25. Because FIFRA prohibits EPA from making the data available to multinational pesticide companies, simply publishing the data, as Plaintiffs allege is required, is in fact legally prohibited. *See* 7 U.S.C. § 136h(g). Instead, as Plaintiffs well know, the data are available on request to any individual who affirms that they do not represent, and will not provide that data to, a multinational pesticide company. *See id.* Plaintiffs' claims should be dismissed.

3. Claims 5-6 (Conditional Registrations)

As EPA explains, Plaintiffs fail to specify the final EPA action(s) they wish to challenge, which conditions of registration were allegedly not met, and when. *See* EPA Mot. at 26-27. These conclusory allegations fail to allege facts that, if true, would show that a condition of registration was unmet. *United States ex rel. Lee v. Corinthian College*, 655 F.3d 984, 991 (9th Cir. 2011).

In this regard, Plaintiffs mention only the first registrations for clothianidin and thiamethoxam, issued in 2003 and 2000, respectively. Plaintiffs allege that unspecified conditions (possibly including a "pollinator field study") of those registrations were required to be met within three years for clothianidin (*i.e.*, by 2006), and two years for thiamethoxam (*i.e.*, by 2002), and that EPA was required to initiate cancellation when the conditions were not met by the deadlines. *See* Am. Compl. ¶¶ 121, 125. However, even if adequately pled, such claims first accrued in 2006 and 2002, respectively, and are barred by the six-year statute of limitations. 28 U.S.C. § 2401(a). In addition, FIFRA lacks a citizen suit provision, and provides no jurisdiction for a third party action challenging an alleged EPA failure to enforce the conditional registration requirements against a registrant. *Fiedler v. Clark*, 714 F.2d 77, 79 (9th Cir. 1983) ("Congress considered and explicitly rejected [authorizing] suits against the EPA . . . for failure to perform nondiscretionary duties or for failure to investigate and prosecute violations."); *see also* EPA Mot. at 30-31, n. 15.

4. Claims 7-8 (Unconditional Registrations)

Plaintiffs allege that EPA issued unconditional registrations for unspecified clothianidin and thiamethoxam products while other such products remain registered conditionally. Am. Compl. ¶¶ 129-32, 135-38. Plaintiffs allege that this is inconsistent or violates FIFRA. *Id.* ¶¶ 132, 138. In addition to failing to identify specific registrations or conditions, or plead any of the other basic facts needed to state a claim, *see* EPA Mot. at 27-28, Plaintiffs also fail to explain why unspecified conditions or gaps associated with some products should preclude the issuance of unconditional registrations for other products that may have different formulations and uses. There is no legal basis for Plaintiffs' view that it would be arbitrary or violate FIFRA for EPA to simultaneously allow an unconditional registration, and a conditional registration, for two different products that contain the same active ingredient. To the contrary, EPA reviews each product individually based on its composition and uses, and has discretion over whether to evaluate a given product under the unconditional or conditional criteria. *See* 7 U.S.C. § 136a(c)(3)(7) (EPA "may" conditionally register a product that meets the criteria); 40 C.F.R. § 152.111 (EPA has "discretion to review applications under either the unconditional . . . or the conditional registration criteria").

5. Claims 9-10 (Suspension)

Plaintiffs allege that EPA violated FIFRA and the APA by failing to suspend clothianidin and thiamethoxam despite Plaintiffs' "repeated[]" requests to do so. Am. Compl. ¶¶ 143, 148.[19] EPA correctly characterizes Claim 9 as either a challenge to EPA's Partial Decision rejecting the "imminent hazard" allegations in the clothianidin Petition, which is duplicative of Claim 1, or a new claim lacking any cognizable legal theory. EPA Mot. at 28-29. In Claim 10, Plaintiffs assert that they "have repeatedly formally requested EPA to suspend the registrations for thiamethoxam products . . . and the agency has refused." Am. Compl. ¶ 148. However, the only "refusal" alleged

[19] Unrelated to any cause of action or final EPA order, Plaintiffs also assert that a pesticide product's "proponent" has a "legal burden of showing that any pesticide and any approved uses meet the FIFRA criteria" to continue to be registered, citing 40 C.F.R. § 154.5. Am. Compl. ¶¶ 142, 147. This assertion is legally incorrect and demonstrates a fundamental misunderstanding of FIFRA. The cited regulation applies where a product has been placed in "Special Review," which is not the case here. "Special Review" is a specific administrative review process under FIFRA, 7 U.S.C. § 136a(c)(8), and EPA regulations lay out detailed standards and procedures that specifically apply in that setting. *See* 40 C.F.R. Part 154.

is EPA's February 27, 2013 letter (*id.* ¶ 88), which did not refuse a suspension request, and does not constitute final agency action subject to judicial review. Ex. 3; *Corinthian College*, 655 F.3d at 991 ("[C]onclusory statements[] do not suffice."); *Fiedler*, 714 F.2d at 79 (no jurisdiction to challenge alleged EPA "failure to investigate and prosecute violations").

6. Claims 11-12 (Labeling)

Plaintiffs allege that unspecified clothianidin and thiamethoxam label "warnings about bee hazards" are "inconsistent across various registered products" and inadequate to advise users how to mitigate potential risks to bees. Am. Compl. ¶¶ 151, 155.[20] Plaintiffs fail to identify the final agency action (*see* EPA Mot. at 30) or the particular label language they wish to challenge.

Under FIFRA, each product has its own label with its own directions for use, which is an integral part of the registration itself and must be approved by EPA for each registration. *See, e.g.*, 7 U.S.C. §§ 136a(c)(5), 136a(f)(1); 40 C.F.R. §§ 152.50(e), 152.108. As Plaintiffs allege, there are at least 103 registrations of products containing clothianidin or thiamethoxam, each with its own composition and uses, and its own label language that differs "across various registered products." Am. Compl. ¶¶ 151, 155, Apps. A, B. Thus, even if Plaintiffs had specified a final EPA action, they have failed to state a claim by failing even to identify the label language they deem inadequate.

7. Claims 2, 13-14 (ESA Claims)

a. Neither EPA's Partial Decision nor Its Continuing Authority Under FIFRA Is an "Action" That Triggers ESA Consultation

ESA §7(a)(2) requires each federal agency to ensure that agency "action" is not likely to jeopardize an ESA-listed species or result in adverse modification of species habitat. 16 U.S.C. § 1536(a)(2). To trigger this requirement, there must be a specific, affirmative "action" taken by the agency. Plaintiffs fail to allege an agency "action" sufficient to trigger ESA obligations.

Claim 2 fails to state a claim because denying a petition is not an agency "action" for purposes of the ESA. *See* EPA Mot. at 21-22. The ESA "mandate[s] consultation . . . only before an

[20] Plaintiffs also assert that EPA insufficiently enforces label warnings to prevent harm from "contaminated dust from planting of treated seeds." Am. Compl. ¶¶ 152, 156. No cause of action is alleged relating to this assertion. Regardless, EPA enforcement decisions are not subject to judicial review. *See Heckler v. Chaney*, 470 U.S. 821, 832-33 (1985); *Fiedler*, 714 F.2d at 79.

agency takes some *affirmative* agency action," such as issuing a license or promulgating a regulation, that may affect a listed species or critical habitat. *Cal. Sportfishing Protection Alliance v. FERC*, 472 F.3d 593, 595 (9th Cir. 2006) (emphasis added). Where there is "no such action . . . there [is] no corresponding duty to consult." *W. Watersheds Project v. Matejko*, 468 F.3d 1099, 1102 (9th Cir. 2006). EPA's denial of the request for suspension is not an affirmative act or authorization, but merely continues the *status quo* under existing authorizations. *See Karuk Tribe v. U.S. Forest Serv.*, 681 F.3d 1006, 1020-21 (9th Cir. 2012) (*en banc*).

Claims 13 and 14 rely on an equally flawed theory: that EPA's "continuing authority over" registrations constitutes "ongoing agency action" and requires a rolling duty to consult under ESA §7(a)(2). The Ninth Circuit rejected this theory *en banc*, holding that "discretionary control and involvement" is not "agency action" requiring consultation under §7(a)(2). *Id.*, 681 F.3d at 1021 ("Where private activity is proceeding pursuant to a vested right or to a previously issued license an agency has no duty to consult under Section 7 if it takes no further affirmative action"); *CBD v. EPA*, 2013 U.S. Dist. LEXIS 57436, at *33 ("Mere discretionary control and involvement will not suffice.").

b. Plaintiffs Fail to Allege Harm to a Specific Listed Species Caused by a Specific Agency Action

Plaintiffs fail to state an ESA claim for the further reason that they fail to allege a specific agency act corresponding to the alleged harm to each of the ESA-listed species. "Plaintiffs must allege a separate ESA claim corresponding to an affirmative act with respect to each of the [identified] pesticides . . . ." *CBD v. EPA*, 2013 U.S. Dist. LEXIS 57436, at *33. Plaintiffs allege only that an undifferentiated list of over 100 EPA activities over 13 years provide the predicate "actions." Am. Compl. ¶¶ 159, 164. These allegations do not suffice. Plaintiffs fail to allege how one or more specific affirmative acts trigger ESA §7(a)(2) and cause harm to a named species in which Plaintiffs allege a cognizable interest. Thus, Claims 13 and 14 fail to state a claim.

c. Plaintiffs' ESA Claims Are Time-Barred

EPA first registered thiamethoxam and clothianidin in 2000 and 2003, respectively, well outside the six-year limitations period. *See id.* ¶ 79. Challenges to those registrations are time-

barred, and Plaintiffs' "continuing authority" theory does not make them timely, as the ongoing use of the pesticides occurs pursuant to the prior authorizations. *Karuk Tribe*, 681 F.3d at 1020-21. While Plaintiffs name over 100 approvals of clothianidin and thiamethoxam products, they ultimately seek relief against the underlying FIFRA registrations of these active ingredients. *See CBD v. EPA*, 2013 U.S. Dist. LEXIS 57436, at *54 ("Plaintiffs' core objections are to the pesticide registrations themselves . . . .") (internal quotations omitted). Hence, challenges to the subsequent, derivative product registrations stemming from the original registrations are also time-barred. *See Cal. Sportfishing*, 472 F.3d at 598-99 (any EPA "action" for ESA purposes concluded when EPA approved the prior registrations); *Hardin*, 625 F.3d at 742. At a minimum, the Court should dismiss claims relating to registrations issued before March 21, 2007, for which the "running of the statute [of limitations] is apparent on the face of the complaint." *Chubb Custom Ins. Co. v. Space Sys./Loral, Inc.*, 710 F.3d 946, 974 (9th Cir. 2013).

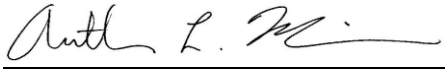
Finally, Plaintiffs failed to allege sufficient facts to allow this Court to determine which, if any, of the EPA activities within the six-year limitations period could trigger §7(a)(2), and whether Plaintiffs have standing with respect to each such activity and species. *See CBD v. EPA*, 2013 U.S. Dist. LEXIS 57436, at *70 ("Plaintiffs [must] plead the specific affirmative act for each pesticide, and that will inform the Court's application of the statute of limitations."). Absent such allegations, Plaintiffs' Claims 13 and 14 must be dismissed.

V. CONCLUSION

For the foregoing reasons, Claims 2-14 and part of Claim 1 should be dismissed for lack of jurisdiction, or alternatively for failure to state a claim.

Respectfully submitted,

Dated: September 16, 2013

By: 

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